

§ 32.16

10 CFR Ch. I (1–1–10 Edition)

product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer

or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide ("americium-241" or "Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978; 72 FR 58487, Oct. 16, 2007; 73 FR 42673, July 23, 2008]

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report

with the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in §30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under §30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under §30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and

(3) The number of units of each type of product transferred during the reporting period by model number, if applicable.

(c)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include data for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under §32.14 shall file a report for the current calendar year within 30 days after ceasing distribution.

(d) If no transfers of byproduct material have been made under §32.14 during the reporting period, the report must so indicate.

(e) The licensee shall maintain the record of a transfer for one year after the transfer is included in a report to the Commission.

[72 FR 58487, Oct. 16, 2007, as amended at 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

§32.18 Manufacture, distribution and transfer of exempt quantities of by-product material: Requirements for license.

An application for a specific license to manufacture, process, produce, package, repack, or transfer quantities of byproduct material for commercial distribution to persons exempt pursuant to §30.18 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter: *Provided, however*, That the requirements of §30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(b) The byproduct material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

(c) The byproduct material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(d) The applicant submits copies of prototype labels and brochures and the Commission approves such labels and brochures.

[35 FR 6428, Apr. 22, 1970, as amended at 43 FR 6922, Feb. 17, 1978]

§ 32.19 Same: Conditions of licenses.

Each license issued under §32.18 is subject to the following conditions:

(a) No more than 10 exempt quantities set forth in §30.71, Schedule B of this chapter shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in §30.71, Schedule B of this chapter, provided that the sum of such fractions shall not exceed unity.